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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,633	07/23/2003	George M. Hutchinson	066243-0166 (128639)	8071

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EXAMINER

RAJAN, KAI

ART UNIT	PAPER NUMBER
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3769

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/625,633	Applicant(s) HUTCHINSON ET AL.	
	Examiner Kai Rajan	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-14,16,17,28,68,69 and 71-84 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-12,16,17,28,68,69 and 71-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Examiner acknowledges the reply filed June 23, 2010.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 – 3, 5 – 12, 16, 17, 28, 68, 69, and 71 – 84 are rejected under 35

U.S.C. 102(e) as being anticipated by Zhou et al. U.S. PGPub No. 2003/0149526 A1.

1. A patient physiologic monitoring assembly comprising:

a plurality of sensors that generate a real-time physiologic data stream, said real-time physiologic data stream including a plurality of physiologic variables (Paragraphs 0022 - 0024

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devices comprise physiological sensors measuring parameters including heart rate, blood pressure, respiration, body temperature, and blood flow rate);

a first logic rule set including a plurality of logic rules for interpreting the plurality of physiologic variables (Paragraphs 0081 – 0084 alert thresholds are stored at a server and on user device. The alert rules on the device comprise basic evaluation rules);

a second logic rule set including a plurality of logic rules for interpreting the physiologic variables (Paragraphs 0081 – 0084, 0088 alert thresholds are stored at a server and on user device. The alert rules applied at the service provider comprise a more sophisticated second level of evaluation using logical rules); and

a controller that receives said real-time physiologic data stream, said controller including a logic that cross references said plurality of physiologic variables with the first logic rule set and second logic rule set (Paragraphs 0081 – 0084, 0088 microcontroller on user device applies first rule set, and service provider applies first and second level rule sets to determine the appropriate alarm notification), and

generates at least a first diagnostic interpretation of said plurality of physiologic variables utilizing said first logic rule set and a second diagnostic interpretation of said plurality of physiologic variable utilizing the said second logic rule set (Paragraphs 0081 – 0084, 0088 a first alarm is generated by applying a first rule set, and an alarm notification is generated depending on the result of the second level sophisticated evaluation).

2. A patient physiologic monitoring assembly as described in claim 1, wherein said logic is further adapted to display said first and second diagnostic interpretations on a display element

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(Paragraphs 0024, 0025, 0081 – 0084, 0088 end users receive notifications of alerts as determined from the first and second rule sets on alert devices).

3. A patient physiologic monitoring assembly as described in claim 1, wherein said logic is further adapted to select said first logic rule set and said second logic rule set from a rules database, said rules database including a plurality of logic rule sets (Paragraphs 0081 – 0093 alert tables are stored at the server database for use by the service provider and devices).

5. A patient physiologic monitoring assembly as described in claim 3, wherein said logic is further adapted to modify one of said plurality of logic rules within said first logic rule set (Paragraphs 0081 - 0093 rules can be added or modified by users or clinicians with access via a website).

6. A patient physiologic monitoring assembly as described in claim 5, wherein said logic edits one of said plurality of logic rules (Paragraphs 0081 - 0093 rules can be added or modified by users or clinicians with access via a website).

7. A patient physiologic monitoring assembly as described in claim 5, wherein said logic deletes one of said plurality of logic rules (Paragraphs 0081 - 0093 rules can be added or modified by users or clinicians with access via a website).

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8. A patient physiologic monitoring assembly as described in claim 5, wherein said logic adds a new logic rule to said first logic rule set (Paragraphs 0081 - 0093 rules can be added or modified by users or clinicians with access via a website).

9. A patient physiologic monitoring assembly as described in claim 3, wherein said logic is further adapted to add a new logic rule set to said rules database (Paragraphs 0081 - 0093 rules can be added or modified by users or clinicians with access via a website).

10. A patient physiologic monitoring assembly as described in claim 1, further comprising a plurality of networked medical facilities in communication with said controller such that said first logic rule set may be received from any of said plurality of networked medical facilities (Paragraphs 0022, 0081 – 0093, 0096 end users entering rules include caregivers, and since multiple end users are linked to the service provider, multiple medical facilities have caregivers networked to the system).

17. The method of claim 11, wherein generating a response based on the application of at least one of the plurality of rule-based algorithms comprises generating an alarm (Paragraphs 0081 - 0084 rules tables are for alarm determination).

68. A patient physiologic monitoring assembly as described in claim 2, wherein said logic is further adapted to receive a selection of the first diagnostic interpretation or the second

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diagnostic interpretation from a clinician (Paragraphs 0022, 0081 – 0093, 0096 end users entering rules include caregivers).

69. The method of claim 11 wherein the plurality of rules of the first rule set are directed towards a general diagnostic interpretation identifying a target body system and the plurality of rules of the second rule set are directed towards creating a specific diagnostic interpretation of a condition within a targeted body system (Paragraphs 0081 – 0084, 0088 alert thresholds are stored at a server and on user device. The alert rules applied at the service provider comprise a more sophisticated second level of evaluation using logical rules).

71. The method of claim 69 wherein the general diagnostic interpretation identifies the cardiac system and the specific diagnostic interpretation identifies a cardiological condition (Paragraphs 0022, 0081 – 0093 cardiac parameters are monitored by sensors, and undergo two sets of evaluation and alarm rules for alarm notification generation)

Claims 11, 12, 16, and 72 – 84 are rejected by the system and method of Zhou as cited above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhou et al.

U.S. PGPub No. 2003/0149526 A1 (“Zhou”) in view of Ali et al. U.S. PGPub No.

2002/0035315 A1 (“Ali”).

Regarding claim 28, Zhou discloses monitoring physiological parameters from multiple patients and applying alert rules that are logic based to determine the need for alert notification according to logic rules stored in a database (see citations above). Zhou fails to disclose calculating confidence scores for the results of evaluations performed on collected data. However, Ali a reference in an analogous art of physiological monitoring and alert detection teaches a confidence based alarm system (Ali paragraphs 0020, 0096, 0098, see also abstract). It would have been obvious to one of ordinary skill in the art of physiological monitoring and diagnosis to apply statistical evaluations and confidence scores of Ali to the evaluations performed in Zhou, since such calculations are routinely performed in the medical diagnostic arts to reduce occurrences of false alarms and improve accuracy (Ali paragraphs 0020, 0096, 0098, see abstract).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kai Rajan whose telephone number is (571)272-3077. The examiner can normally be reached on Monday - Friday 9:00AM to 4:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on 571-272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kai Rajan/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit
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August 28, 2010